BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the amendment of	) NOTICE OF AMENDMENT
ARM 37.104.101 and 37.104.212	)
pertaining to emergency medical	)
services (EMS)	)

TO: All Concerned Persons

1. On November 10, 2011, the Department of Public Health and Human Services published MAR Notice No. 37-569 pertaining to the public hearing on the proposed amendment of the above-stated rules at page 2382 of the 2011 Montana Administrative Register, Issue Number 21.

2. The department has amended ARM 37.104.101 as proposed.

3. The department has amended the following rule as proposed, but with the following changes from the original proposal, new matter underlined, deleted matter interlined:

37.104.212 RECORDS AND REPORTS (1) remains as proposed.
(2) ~~No later than January 1, 2012 a~~Ambulance services and nontransporting units must provide data as identified by the department in this rule.
(3) through (12) remain as proposed.

AUTH: 50-6-323, MCA
IMP: 50-6-323, MCA

4. The department has thoroughly considered the comments received. A summary of the comments received and the department's responses are as follows:

COMMENT #1: Several commenters stated that the mandatory collection of the required data in these proposed rules is too much information; is difficult and time consuming to do, and will be a burden on volunteer services.

RESPONSE #1: The department is confident that data submission will not be an undue burden and it is appreciative of the services that are already providing data or preparing to provide data. Many services are already using electronic patient care record software that allows them to export required data into the department server with minimal effort. Services continuing to use paper patient care records will find that the department provided software will require only a few minutes time to provide minimum data for most incidents.

COMMENT #2: Several commenters expressed concerns that EMS services unable to provide required data will lose their license. Additionally, commenters wanted to know what penalties for noncompliance to these rules will be.

RESPONSE #2: While the department has authority to cancel a license, such action occurs only pursuant to legal processes provided in statute for a service refusing to remedy or correct a violation. Additionally, any service demonstrating a hardship to meeting these rules may apply for a waiver as provided for in 50-6-325, MCA. Rather than penalties per se, the department plans to implement strategies such as stipulating only services that provide required data will be eligible for future grants.

COMMENT #3: One commenter stated that the department should be required to develop a user-friendly electronic patient care record or allow services to utilize paper forms that can be used to scan data into a data system.

RESPONSE #3: The department has developed a web-based, user-friendly patient care record software product that is available free of charge to any EMS service. The department is constantly implementing enhancements and improvements to this program and it will be forming a data workgroup in 2012 to solicit input on continued improvements. While paper-based data collection has been attempted by several states, none of those systems were able to successfully scan paper data without substantial, time-consuming error correction procedures for the services and states.

COMMENT #4: Two commenters stated that fire departments are already required to provide EMS data to the National Fire Incident Reporting System (NIFRS) data system and that these proposed requirements to provide National EMS Information System (NEMSIS) data should be integrated in order to avoid duplication of effort.

RESPONSE #4: While entry of EMS data into NIFRS is not required, the department recognizes that many fire departments provide such data voluntarily. Only 25 of the 200+ fire departments are affected by these proposed rules and the department is aware that at least some of these departments already have software that allows submission of both NFIRS and NEMSIS data with negligible effort. While similar to NFIRS, the NEMSIS data set is better constructed for EMS system evaluation purposes. The department will provide technical support and training to any service needing assistance. Any ambulance service, that finds it has a hardship meeting these requirements, will be able to apply for a waiver as described under 50-6-325, MCA.

COMMENT #5: Several commenters stated that these requirements are an unfunded mandate and that EMS services do not have funding to meet the computer, internet, and other technical requirements to submitting required data.

RESPONSE #5: All licensed EMS services are already providing much of the information required under proposed ARM 37.104.212(4) as part of their ongoing licensing application. The entry of minimum data required under ARM 37.104.212(5) will be accomplished through the same department software and will not require any additional investment by EMS services.

COMMENT #6: One commenter stated that most EMS agencies already have report processes in place to report on their patient care.

RESPONSE #6: While many EMS services are collecting data for their purposes, a key finding in a 2008 legislative audit was that the department did not have a data system that could adequately describe Montana's EMS system. Key recommendations of that audit included the need for the department to develop a data system that could be used to evaluate and improve components of the EMS system and to improve patient access to prehospital care.

COMMENT #7: One commenter asked whether nontransporting units are required to provide data under these proposed rules.

RESPONSE #7: Proposed ARM 37.104.212(7) states that nontransporting units are not required to submit NEMSIS data, but may do so if they wish.

COMMENT #8: One commenter asked several questions related to states that provide data to the NEMSIS including how many states have implemented mandatory electronic reporting; how many reporting states have a high percentage of volunteer services; and how many states provide financial support to EMS service reporting activities.

RESPONSE #8: A national survey of states released recently shows that 39 states currently have the ability through law or regulation to require local EMS agencies to collect and submit EMS data. An additional eight states currently do not require data submission but plan to in the next few years. Thirty-three states and territories are now providing data to the national database and many of those states (e.g., Idaho, North Dakota) are rural like Montana. Twenty percent of the 22 million records currently in the national database come from volunteer services. This is comparable to the department's estimate that 16% of EMS incidents will come from volunteer services. States implementing electronic data collection have supplied software and training free of charge to EMS services as the financial incentive. Over two dozen Montana services are using software the department has developed and made available at no cost to any service.

COMMENT #9: One commenter stated that much of the required data has little to do with quality improvement or quality assurance of patient care.

RESPONSE #9: NEMSIS is a national effort to create a database of information about local and state agencies that will describe EMS in a fashion previously not possible and to utilize that data to improve patient care. Within the larger NEMSIS data set of over 400 data elements, federal, state and many professional organizations collaborated on a national, minimum data set that could be used to evaluate and improve EMS systems. The minimum data required under these rules will enable the department to evaluate the EMS system and to develop strategies that will improve patient care. As one of many examples, the department could

utilize NEMSIS data to evaluate delays in getting trauma or stroke patients to definitive care and to then develop strategies to decrease causes of such delays.

COMMENT #10: Two commenters noted that proposed rules require every entity involved with a patient's care to complete a patient record on that patient and this will result in duplicate entry of data and inaccurate reports.

RESPONSE #10: While only ambulance services will be required to provide data, the department does want to obtain data from all EMS services on a call. This strategy will enable evaluation of all components of the EMS system and how they may affect patient outcomes. There are several fields in the minimum data set that will enable the department to accurately describe multi-patient and multi-service responses for statistical purposes.

COMMENT #11: Two commenters stated that these rules require EMS services to use the department's software to collect patient care information during a call and that there are significant technological and legal barriers to accomplishing this.

RESPONSE #11: These proposed rules only require ambulance services to provide minimum data into the department data server at least quarterly. While these rules do not require services to use software to collect an entire patient record, many services are using technologies such as tablets or other processes to collect patient information without duplication of effort or loss of data. Additionally, the department will be introducing tablet-based data entry functionality in 2012 that will help the two dozen services using the department's software to safely and reliably collect patient information while on a run.

COMMENT #12: One commenter questioned why demographic information about EMS personnel is necessary.

RESPONSE #12: To properly administer programs such as EMS service licensing, the department collects demographic information. Additionally, workforce issues are one of the most pressing challenges to the viability of EMS services and the department is collecting demographic information in order to develop strategies to improve the recruitment and retention of EMS providers, especially volunteers.

COMMENT #13: A commenter stated that vehicle hours and mileage are not good indicators of the condition or reliability of an EMS vehicle and that such information is already collected during EMS service inspections.

RESPONSE #13: Information about the vehicle's age and mileage will help the department characterize the overall state of Montana's ambulance fleet. While such information has historically been documented every two years during inspections, it would now be collected annually and be available in the data system for analysis and reports.

COMMENT #14: A commenter stated that implementation of this rule change seems abrupt and that services have not had enough time to prepare for these changes.

RESPONSE #14: The department started this process nearly two years ago with distribution of draft rules and informational sessions. A hearing was held in the spring of 2011 and additional informational opportunities have been provided over the summer. The department feels that EMS services have had adequate notice that such changes were being proposed. Due to adoption of these rules occurring in mid-January 2012, we are changing the effective date of these rules to April 1, 2012. This will give the department adequate time to provide education and technical assistance to ambulance services that will be providing data.

COMMENT #15: A commenter questioned why EMS should have to submit such detailed reporting while other healthcare services do not.

RESPONSE #15: These proposed rules require only minimum data be submitted by ambulance services. Reporting of healthcare data to the department for other purposes and reporting of data by healthcare providers, such as for hospital accreditation or JCAHO, is very common in the healthcare industry.

COMMENT #16: A commenter stated that the Board of Medical Examiners is responsible for patient care; that the department is responsible for ambulance service, and that data elements related to patient care are not related to the safe operation of the service itself.

RESPONSE #16: The department has been mandated through several statutes including 50-6-102, 50-6-301, 50-6-401, MCA for the protection of the health and safety of the Montana's citizens and visitors. Again, a 2008 legislative audit highlighted the need for the department to develop an information system to support its regulatory responsibilities. Collection of minimum patient information is necessary in order to evaluate the response of prehospital services on patients who suffer illness and injury and to enable the department to develop strategies to improve patient outcomes.

COMMENT #17: A commenter suggested that data collection should only be required from larger ambulance services that are already using electronic patient records and that data from smaller services should be optional.

RESPONSE #17: As noted in a 2008 legislative audit, the department does not have a comprehensive data system that can be used to describe EMS services and to be able to advocate for improvements to the EMS system. The department needs to obtain data from all EMS services and it will work with all services to enable them to provide data with as little burden as possible.

COMMENT #18: A commenter stated that the department already has rules mandating reporting that have never been enforced and that he feels current rules should be enforced instead of proposed rules. Another commenter stated that the department has had data reporting authority for thirty years; has never previously

made any attempt to collect data and has now proposed rules for a massive, excessively detailed process that will require all services additional costs.

RESPONSE #18: Current requirements in ARM 37.104.212(4) requiring services to report the number and types of runs, the type of emergency, and average response times quarterly is very vague and only useful for statistical purposes. Data collection and analysis has been the foundation of improved outcomes for patients in the trauma system and the department now needs to follow the lead of 33 other states that are participating in the NEMSIS project to collect data that can be used to evaluate and improve patient care.

COMMENT #19: A commenter stated that proposed rules are confusing as they reference the entire NEMSIS data set but then only require minimum data collection. The commenter also states that rules contain many unnecessary items, items that are not the business of a state regulatory agency and that such data collection may be a violation of personal privacy.

RESPONSE #20: Under proposed ARM 37.104.212 (4) and (5), EMS services are required to provide minimum data about their EMS service and their patients. Proposed ARM 37.104.212(7) states that EMS services are not required to submit other NEMSIS data elements, but may do so. As such, proposed ARM 37.104.212(9) adopts the entire NEMSIS data standard so that any data provided is in the NEMSIS standard. While the commenter provided no detail about what items are unnecessary or of concern to personal privacy, it is the policy of the department to protect the confidentiality of private information and to ensure that access to such information is restricted to legitimate purposes of program administration.

COMMENT #20: A commenter stated that ARM 37.104.212(8) requires the department to consult (thus approve) software purchases. He also stated that this conflicts with another section that only requires services to provide minimum data.

RESPONSE #20: Software to collect electronic patient care data represents a significant investment for EMS services. Under these rules, services purchasing electronic patient care record software will only be required to consult with the department in order to assure that their investment will be for software that is NEMSIS certified and capable of submitting required data. The department will not involve itself further with the approval of purchases or selection of specific vendors.

COMMENT #21: A commenter stated concern for the risk to EMS services that choose to use the department web server when there is no dedicated funding to assure its availability regardless of funding priorities in the future.

RESPONSE #21: Using a variety of funding strategies, the department has funded the development and maintenance of its EMS software for over six years and a trauma registry for over 20 years. This data collection project is a high priority for the department and it will continue to support the EMS data system through any variety of funding strategies as needed.

COMMENT #22: A commenter expressed that he had numerous concerns as to the privacy and violation thereof for both patients and EMT providers under these data collection requirements.

RESPONSE #22: There is no protected health information within the minimum data required under these rules. For services who wish to provide more than the minimum data, HIPAA statutes such as 45 C.F.R. § 164.512(b)(1) clarify that covered entities may disclose protected health information without an individual's authorization to a public health authority, such as the department, for the purpose of public health activities. Data submitted to the department is stored on state data servers. Under 2-17-534, MCA, the Department of Administration is responsible for providing centralized management and coordination for security of data and information technology resources. Confidential information is protected by statutes and data policies. In addition to security implemented by the Department of Administration, the department's software incorporates state-of-the-art security including password-protected and permission-based access.

COMMENT #23: A commenter stated that proposed rules will place a burden on the private and public sector and even though they will provide the majority of the data, they will not be eligible for funding realized from such data and that they will never have a return on their investment or effort.

RESPONSE #23: All of the private and other large services the department has met with currently utilize electronic data systems that will enable them to submit the required data to the department with little effort. It is the intent of the department to consider all services that provide data when determining eligibility for future funding opportunities that become available.

COMMENT #24: Two commenters asked about what the value is of data collection for EMS services and Montana communities.

RESPONSE #24: Research demonstrates that collection and analysis of data to evaluate the EMS system improves patient care and patient outcomes. Collection of system data as required under these rules is a core function of public health and the department will utilize such data to help EMS services and other parts of the emergency care system provide better patient care and improve the community's health.

     5. These rule amendments are effective April 1, 2012.

Rule Reviewer	Anna Whiting Sorrell, Director
	Public Health and Human Services

     Certified to the Secretary of State January 17, 2012